

REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Rejection of Claims 2-4 Under 35 U.S.C. 103(a)

The Examiner has maintained the rejection of claims 2-4 under Section 103(a) as being obvious over U.S. Patent Appln. Publication No. 2002/0009738 A1 (Houghton et al.). In particular, the Examiner acknowledges that the publication does not teach a method of detecting a combination of polypeptides in a test sample with at least two antibodies with the subsequent formation of antigen/antibody complexes of each member of the combination by an immunoassay and resulting in the indication of breast cancer in a patient. However, the Examiner alleges that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use antibodies *via* an immunoassay in the detection of the taught breast tumor proteins in a patient sample within a tissue section or cell culture.

In response, Applicants respectfully traverse the Section 103(a) rejection of claims 2-4 over U.S. Patent Appln. Publication No. 2002/0009738. As stated previously, the Houghton et al. document discloses the identification of tissue-specific polynucleotides and methods for determining the presence of cancer in a patient by detecting polynucleotides which encode breast tumor proteins. It must be noted, however, that the polynucleotides of the Houghton et al. document do not necessarily encode expressed proteins. In particular, there are many polynucleotides which are never translated and therefore a corresponding encoded polypeptide may not be detected either in tissue or in the circulation. Thus, the Examiner's statement that "It would follow that

the detection of encoded polypeptides would be useful in the diagnosis of breast cancer” is not accurate, as some polynucleotides do not result in detectable, encoded proteins.

As evidence of the above argument, attached hereto is a Declaration signed by Dr. Barry Dowell. In particular, Dr. Dowell states in the Declaration that “[i]t is certainly not obvious that because a gene is expressed, the encoded protein is automatically expressed as well as secreted.” (See page 3, first full paragraph, Declaration.) Further, Dr. Dowell notes that, since all expressed polynucleotides do not result in increased expression of the respective encoded proteins, it would not have been obvious that measuring the polypeptide of interest would be useful from a diagnostic standpoint. (See page 3, first full paragraph, Declaration.) Thus, it is submitted that the above arguments as well as Declaration of Dr. Barry Dowell overcome the Examiner’s Section 103(a) rejection.

Also, it must be reiterated that, in contrast to the disclosure of Houghton et al., the claimed invention relates to the detection of **actual polypeptide markers (or complexes thereof) present in specific combinations**. Presence of the specific combination of proteins or presence of antibody-antigen complexes of each protein of a specific combination is indicative of a diagnosis of breast cancer. One is not utilizing polynucleotides in any manner. **Rather, one is utilizing the presence of specific combinations of expressed proteins markers, or complexes including the markers, for purposes of diagnosis**. In particular, in his Declaration, Dr. Dowell contends that the presence of two polynucleotides would not have rendered obvious or motivated the skilled artisan to predict the presence of the two encoded proteins of a specific combination. (See page 3, first full paragraph, Declaration.) Dr. Dowell also states that the use of separate antibodies to separately identify each member of the combinations of

the specific polypeptides of the claimed invention is also certainly not obvious. (See page 3, first full paragraph, Declaration.) Thus, the presently claimed invention is quite distinct from the teachings and suggestions of Houghton et al. The polynucleotides of Houghton et al. would not have motivated one of ordinary skill in the art to utilize the polypeptide markers of the present invention, much less in the specific combinations of these markers recited in the claims.

Further, it should also be noted that MPA is neither disclosed nor suggested in the Houghton et al. document.

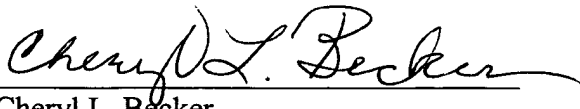
In view of the above and the Declaration of Dr. Barry Dowell, it is submitted that one of ordinary skill in the art certainly would not have been motivated to have created the claimed invention based upon the teachings and suggestions of Houghton et al. The Section 103 rejection has been overcome and should be withdrawn accordingly.

In conclusion, it is believed that the subject application is in condition of allowance and Notice to that effect is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,
J. Henslee, et al.

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